

# Medical Device/Equipment ALERT

Ref. MDEA(NI)2007/36

Issued: 26 April 2007

For:

IMMEDIATE ACTION	
<b>ACTION</b>	✓
UPDATE	
INFORMATION	



**HEALTH ESTATES**

creating healing environments

	Section
<b>Medical Device/Equipment:</b> Umbilical cord clamp clipper manufactured by Unomedical Ltd.	▶ ①
<b>Problem:</b> There is potential for the blade to fall out of the product or break during use of identified lots.	▶ ②
<b>Action by:</b> Maternity units, midwifery departments, neonatal intensive care units, midwives in the community.	▶ ③
<b>Action:</b> <ul style="list-style-type: none"> <li>• Check stock and quarantine affected lots.</li> <li>• Return affected products to the manufacturer for replacement (contact details on page 2).</li> </ul>	▶ ④
<b>Distributed by NIAIC to:</b> <ul style="list-style-type: none"> <li>Chief Executive of each HSS Board</li> <li>Chief Executive of each HSS Trust</li> <li>Chief Executive of each Agency</li> <li>NIAIC Liaison Officers</li> </ul>	▶ ⑤
<b>Contacts</b> Details of manufacturer contacts and NIAIC contacts for technical aspects.	▶ ⑥
<b>Feedback Requirements to NIAIC</b> None Required	▶ ⑦

This Alert is on our web site: <http://www.dhsspsni.gov.uk/niaic>

## 1. DEVICE/EQUIPMENT:

Unomedical umbilical cord clamp clipper (manufacturer product reference 84006182) lots manufactured and distributed between August 2005 and October 2006, they have been distributed in the UK mainly by Unomedical and Southern Syringe Ltd. This is a sterile, single-use device.

## 2. PROBLEM:

Six complaints of the blade falling off or breaking during use were received by the manufacturer in 2006. The moulding tool has now been modified to resolve the problem and the quality assurance improved to ensure correct positioning of the tool. Specific lots manufactured and distributed between August 2005 and October 2006 are being recalled by the manufacturer. This recall was started in November 2006 but the MHRA is concerned that affected devices may still be with users. A copy of the manufacturer's recall notice is available on the MHRA website ([www.mhra.gov.uk](http://www.mhra.gov.uk)).

## 3. ACTION BY:

Maternity units, midwifery departments, neonatal intensive care units, midwives in the community.

## 4. ACTION:

- Check stock and quarantine affected lots.
- Return affected products to the manufacturer for replacement (contact details below).

## 5. ONWARD DISTRIBUTION TO:

Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution to:

- Clinical governance leads
- Heads of midwifery
- Independent Health and Social Care Providers – Private Hospitals & Clinics through RQIA
- Maternity units
- Medical directors
- Midwifery staff
- Neonatal intensive care units
- Nursing executive directors
- Obstetricians
- Purchasing managers
- Risk managers
- Supplies managers

## 6. CONTACTS:

Enquires to manufacturer should be addressed to:

Jackie Taylor  
Customer Research Manager  
Unomedical  
Thornhill Road  
Redditch  
B98 9NL

Tel: 01527 587 700  
Fax: 01527 615 586

E-mail: [jackie.taylor@unomedical.com](mailto:jackie.taylor@unomedical.com)

Enquires to NIAIC should quote reference number MDEA(NI)2007/36 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)  
Health Estates  
Estate Policy Directorate  
Stoney Road  
Dundonald  
Belfast BT16 1US

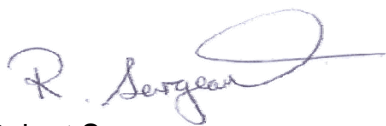
Tel: 028 9052 3868

Fax: 028 9052 3900

Email: [NIAIC@dhsspsni.gov.uk](mailto:NIAIC@dhsspsni.gov.uk)

## 7. FEEDBACK:

None Required



Robert Sergeant  
NIAIC Operational Manager

### HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in MDEA(NI)2006/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at [www.dhsspsni.gov.uk/niaic](http://www.dhsspsni.gov.uk/niaic)

*Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety*